

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

EDITH J. CARR and,)	Civil Action No.: 6:17-cv-393-ORL-KRS
DAVID MIDDLETON CARR,)	
)	
Plaintiffs,)	
)	
v.)	
)	JURY TRIAL DEMANDED
JOHNSON & JOHNSON and)	
ETHICON, INC.,)	
)	
Defendants.)	

**ANSWER AND DEFENSES OF DEFENDANT
JOHNSON & JOHNSON TO PLAINTIFFS' COMPLAINT**

Defendant Johnson & Johnson (“Johnson & Johnson”), by and through its attorneys, responds to Plaintiffs’ Complaint (“Complaint”) as follows.

RESPONSE TO “PARTIES”¹

1. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiffs’ Complaint, and, therefore, denies those allegations.
2. Johnson & Johnson admits only that it is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson denies the remaining allegations contained in Paragraph 2 of Plaintiffs’ Complaint.
3. Johnson & Johnson admits only that it is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New

¹ The repetition of the Complaint’s subheadings is done solely for organizational purposes and is not an admission as to their truth.

Jersey. Johnson & Johnson does not design, develop, manufacture, test, market, promote, distribute, package, label or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Johnson & Johnson admits that Ethicon, Inc. is a New Jersey corporation with its principal place of business in Somerville, New Jersey, and is a subsidiary of Johnson & Johnson. Johnson & Johnson admits that Ethicon, Inc.'s Physiomesh has been available for purchase in the State of Florida. Johnson & Johnson denies the remaining allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. Johnson & Johnson admits that Ethicon, Inc. has researched, developed, tested, manufactured, produced, marketed, promoted and sold Ethicon, Inc.'s Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, develop, test, manufacture, produce, market, promote or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 5 of Plaintiffs' Complaint.

6. Johnson & Johnson admits only that Ethicon, Inc. has researched, developed, tested, manufactured, produced, marketed, promoted, distributed and sold Ethicon, Inc.'s Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, develop, test, manufacture, produce, market, promote, distribute or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 6 of Plaintiffs' Complaint.

7. Johnson & Johnson denies the allegations contained in Paragraph 7 of Plaintiffs' Complaint.

8. Johnson & Johnson denies the allegations contained in Paragraph 8 of Plaintiffs' Complaint.

RESPONSE TO “JURISDICTION AND VENUE”

9. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 9 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusions.

10. Johnson & Johnson denies the allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 11 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusions.

RESPONSE TO “FACTS COMMON TO ALL COUNTS”

12. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint.

13. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. has researched, designed, developed, tested, manufactured, produced, marketed, promoted, distributed, and sold Ethicon, Inc.'s Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, design, develop, test, manufacture, produce, market, promote, distribute or sell any product. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the third sentence of Paragraph 13 of Plaintiffs' Complaint, and therefore, denies those allegations. Johnson & Johnson denies the remaining allegations contained in Paragraph 13 of Plaintiffs' Complaint.

14. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. has designed, manufactured, and sold Ethicon, Inc.'s Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture, or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 14 of Plaintiffs' Complaint.

15. Johnson & Johnson admits only that Ethicon, Inc.'s Physiomesh is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 15 of Plaintiffs' Complaint.

16. Johnson & Johnson denies the allegations contained in Paragraph 16 of Plaintiffs' Complaint.

17. Johnson & Johnson denies the allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. Johnson & Johnson denies the allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Johnson & Johnson denies the allegations contained in Paragraph 19 of Plaintiffs' Complaint.

20. Johnson & Johnson denies the allegations contained in Paragraph 20 of Plaintiffs' Complaint.

21. Johnson & Johnson denies the allegations contained in Paragraph 21 of Plaintiffs' Complaint.

22. Johnson & Johnson denies the allegations contained in Paragraph 22 of Plaintiffs' Complaint.

23. Johnson & Johnson denies the allegations contained in Paragraph 23 of Plaintiffs' Complaint.

24. Johnson & Johnson denies the allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 25 of Plaintiffs' Complaint.

26. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 26 of Plaintiffs' Complaint.

27. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 27 of Plaintiffs' Complaint.

**RESPONSE TO "COUNT I
STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN"**

28. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 28 of Plaintiffs' Complaint.

29. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that

allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 29 of Plaintiffs' Complaint.

30. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson admits only that Ethicon, Inc. has designed, manufactured, and sold Ethicon, Inc.'s Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Johnson & Johnson denies the allegations contained in Paragraph 31 of Plaintiffs' Complaint.

32. Johnson & Johnson denies the allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Johnson & Johnson denies the allegations contained in Paragraph 33 of Plaintiffs' Complaint.

34. Johnson & Johnson denies the allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Johnson & Johnson denies the allegations contained in Paragraph 35 of Plaintiffs' Complaint.

36. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 36 of Plaintiffs' Complaint.

37. Johnson & Johnson denies the allegations contained in Paragraph 37 of Plaintiffs' Complaint.

38. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 38 of Plaintiffs' Complaint.

39. Johnson & Johnson denies the allegations contained in Paragraph 39 of Plaintiffs' Complaint.

**RESPONSE TO "COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN"**

40. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Johnson & Johnson denies the allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Johnson & Johnson denies the allegations contained in Paragraph 43 of Plaintiffs' Complaint.

44. Johnson & Johnson denies the allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. Johnson & Johnson denies the allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. Johnson & Johnson denies the allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. Johnson & Johnson denies the allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Johnson & Johnson denies the allegations contained in Paragraph 48 of Plaintiffs' Complaint.

49. Johnson & Johnson lacks sufficient knowledge or information to know whether Plaintiff Edith Carr used any of Ethicon, Inc.'s products, and Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Johnson & Johnson denies the allegations contained in Paragraph 50 of Plaintiffs' Complaint.

**RESPONSE TO "COUNT III
NEGLIGENCE"**

51. Johnson & Johnson admits only that Ethicon, Inc. has certain duties imposed on it by law, but denies that Ethicon, Inc. breached any duty. Johnson & Johnson denies the remaining allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Johnson & Johnson denies the allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Johnson & Johnson denies the allegations contained in Paragraph 53 of Plaintiffs' Complaint.

**RESPONSE TO “COUNT IV
PUNITIVE DAMAGES”**

54. Johnson & Johnson denies the allegations contained in Paragraph 54 of Plaintiffs' Complaint.

**RESPONSE TO “COUNT V
LOSS OF CONSORTIUM”**

55. Johnson & Johnson incorporates by reference its responses to the allegations contained in Paragraphs 12 through 54 of Plaintiffs' Complaint.

56. Johnson & Johnson denies the allegations contained in Paragraph 56 of Plaintiffs' Complaint.

Johnson & Johnson denies the allegations contained in the unnumbered “Wherefore” Paragraph directly following Paragraph 56 of Plaintiffs' Complaint, and denies that Plaintiffs are entitled to any recovery or any form of relief.

Johnson & Johnson denies the allegations contained in the last Paragraph under COUNT V of Plaintiffs' Complaint, and denies that Plaintiffs are entitled to any recovery or any form of relief.

Johnson & Johnson denies any and all allegations contained in Plaintiffs' Complaint not specifically admitted hereinabove.

DEFENSES

FIRST DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product allegedly at issue in this action.

SECOND DEFENSE

Johnson & Johnson has never had possession or control over the product at issue in this action, and therefore the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

THIRD DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted.

FOURTH DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

FIFTH DEFENSE

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

SIXTH DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction.

SEVENTH DEFENSE

Certain of Plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

EIGHTH DEFENSE

Venue in this Court is improper, and this matter should be dismissed on forum non conveniens grounds.

NINTH DEFENSE

The improper joinder of Plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state, as well as the applicable Rules of Civil Procedure and the laws of the applicable state.

TENTH DEFENSE

The improper joinder of Defendants violates the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state.

ELEVENTH DEFENSE

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in Florida or any other state whose law is deemed to apply in this case.

TWELFTH DEFENSE

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the product at issue is regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

THIRTEENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times, however, the product was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

FOURTEENTH DEFENSE

Plaintiffs' claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

FIFTEENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs' claims nevertheless are barred because the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product complied with all applicable state and federal statutes regarding the product at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiffs' claims are not barred, Johnson & Johnson and the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product is entitled to a presumption that the product at issue is free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

SIXTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA

under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder.

SEVENTEENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. However, Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because the entity responsible for the design, development, manufacture, licensing, marketing, distribution, sale and/or placing the product in the stream of commerce complied with all applicable statutes and with the requirements and regulations of the FDA.

EIGHTEENTH DEFENSE

Any claims by Plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Johnson & Johnson to petition the government.

NINETEENTH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the products at issue in this action. In any event, Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

TWENTIETH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the product at issue in this action. In any

event, Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by Plaintiffs is subject to the exclusive regulations of FDA.

TWENTY-FIRST DEFENSE

Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a safer design for the product at issue.

TWENTY-SECOND DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue provided a benefit to users of such product and greatly outweighed any risk created by using such product, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

TWENTY-THIRD DEFENSE

Johnson & Johnson made no express or implied representations or warranties of any kind to Plaintiffs, nor did Plaintiffs rely on any representations or warranties made by Johnson & Johnson to others. To the extent Plaintiffs relied upon any representations or warranties, such reliance was unjustified.

TWENTY-FOURTH DEFENSE

Any express or implied warranties alleged to have been made by Johnson & Johnson were disclaimed.

TWENTY-FIFTH DEFENSE

Johnson & Johnson did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Plaintiffs and Johnson & Johnson, and/or by Plaintiffs' failure to give Johnson & Johnson timely

notice of the alleged breach of warranty and an opportunity to cure. Johnson & Johnson further specifically pleads as to any breach of warranty claim all affirmative defenses available to Johnson & Johnson under the Uniform Commercial Code, as enacted in Florida or any other state whose law is deemed to apply in this case, and under the common law principles of Florida or any other state whose law is deemed to apply in this case.

TWENTY-SIXTH DEFENSE

Plaintiffs' claim for punitive damages is barred because the product at issue was manufactured and labeled in accordance with the terms of FDA's clearance of the product at issue.

TWENTY-SEVENTH DEFENSE

To the extent that any of Plaintiffs' claims can be, or are construed as, alleging a violation of consumer protection laws, Johnson & Johnson specifically pleads all affirmative defenses available to Johnson & Johnson under the rules and statutes of Florida and/or any state whose law is deemed to apply in this case, and under the common law principles of Florida and/or any state whose law is deemed to apply in this case.

TWENTY-EIGHTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Johnson & Johnson given the state of scientific knowledge and state of the art at the time of the alleged injuries. At all times relevant, the product at issue conformed to state-of-the-art specifications and state of scientific knowledge for such product at that time, as well as all applicable statutes and regulations, including those of FDA.

TWENTY-NINTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that Plaintiffs seek to recover herein.

THIRTIETH DEFENSE

Plaintiffs’ claims are barred, in whole or in part, because the entity responsible for the product acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of the product at issue.

THIRTY-FIRST DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times herein, however, the product in question was manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

THIRTY-SECOND DEFENSE

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which Plaintiff claims is open, obvious, and/or a matter of common knowledge.

THIRTY-THIRD DEFENSE

Plaintiffs’ claims are barred in whole or in part because the product at issue was consistent with and/or exceeded consumer expectations.

THIRTY-FOURTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs’ claims are barred in whole

or in part, however, because the product at issue was at all times properly prepared, packaged, and distributed and was not defective or unreasonably dangerous.

THIRTY-FIFTH DEFENSE

Adequate and complete warnings and instructions were provided with the product at issue. Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. The product at issue, however, was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

THIRTY-SIXTH DEFENSE

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the product were presumptively adequate.

THIRTY-SEVENTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

THIRTY-EIGHTH DEFENSE

Johnson & Johnson is not liable to Plaintiffs because the end users of the product at issue, Plaintiff's physician(s), were sophisticated users of the product.

THIRTY-NINTH DEFENSE

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or

comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of Florida or any other applicable state.

FORTIETH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by Plaintiffs' own fault, which bars or proportionately reduces Johnson & Johnson's liability, if any, for Plaintiffs' alleged damages.

FORTY-FIRST DEFENSE

Plaintiffs voluntarily and unreasonably chose to encounter known dangers.

FORTY-SECOND DEFENSE

The liability of Johnson & Johnson, if any, for Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of Florida or any other state whose law is deemed to apply in this case.

FORTY-THIRD DEFENSE

In the event Johnson & Johnson is held liable to Plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FORTY-FOURTH DEFENSE

There is no causal relationship between Johnson & Johnson's conduct and the injuries and damages alleged by Plaintiffs in the Complaint.

FORTY-FIFTH DEFENSE

At all times mentioned herein, Plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of Plaintiffs bars in whole or in part the damages which Plaintiffs seek to recover herein.

FORTY-SIXTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product.

FORTY-SEVENTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FORTY-EIGHTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility.

FORTY-NINTH DEFENSE

Johnson & Johnson expressly denies any third party engaging in the acts alleged by Plaintiffs was acting as Johnson & Johnson's agent or servant, at the instruction of Johnson & Johnson, or within its control. Therefore, Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FIFTIETH DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Johnson & Johnson.

FIFTY-FIRST DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

FIFTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

FIFTY-THIRD DEFENSE

The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to preserve evidence necessary to the determination of the claims.

FIFTY-FOURTH DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any Plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of Plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than Plaintiff, or, if not disclosed by Plaintiff on the

schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

FIFTY-FIFTH DEFENSE

Some or all of Plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of Florida or any other state whose law is deemed to apply in this case.

FIFTY-SIXTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

FIFTY-SEVENTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

FIFTY-EIGHTH DEFENSE

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

FIFTY-NINTH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SIXTIETH DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts.

SIXTY-FIRST DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

SIXTY-SECOND DEFENSE

Any recovery by Plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SIXTY-THIRD DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted for costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SIXTY-FOURTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and Florida or any other applicable state.

SIXTY-FIFTH DEFENSE

Johnson & Johnson asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of Florida or any other applicable state.

SIXTY-SIXTH DEFENSE

Johnson & Johnson specifically pleads as to Plaintiffs' strict liability claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of Florida or any other state whose law is deemed to apply in this case, and under any common law principles of Florida or any other state whose law is deemed to apply in this case.

SIXTY-SEVENTH DEFENSE

Johnson & Johnson specifically pleads as to Plaintiffs' negligence claims all affirmative defenses available to Johnson & Johnson under the rules and statutes of Florida or any other state whose law is deemed to apply in this case, and under any common law principles of Florida or any other state whose law is deemed to apply in this case.

SIXTY-EIGHTH DEFENSE

Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

SIXTY-NINTH DEFENSE

The Complaint fails to state facts sufficient to entitle Plaintiffs to an award of punitive damages.

SEVENTIETH DEFENSE

No act or omission of Johnson & Johnson was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SEVENTY-FIRST DEFENSE

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of

such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Johnson and Johnson's conduct within the State where Plaintiff resides, or in any other way subjecting Johnson & Johnson to impermissible multiple punishment for the same alleged wrong.

SEVENTY-SECOND DEFENSE

Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

SEVENTY-THIRD DEFENSE

With respect to Plaintiffs' demand for punitive damages, Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*,

517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

SEVENTY-FOURTH DEFENSE

Johnson & Johnson specifically pleads as to Plaintiffs' claims for punitive damages, all affirmative defenses available to Johnson & Johnson under the rules and statutes of Florida and any state whose law is deemed to apply in this case, and under any common law principles of Florida and any state whose law is deemed to apply in this case.

SEVENTY-FIFTH DEFENSE

Johnson & Johnson reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

DEMAND FOR JURY TRIAL

Johnson & Johnson demands trial by jury of all issues so triable as a matter of right.

WHEREFORE, Defendant Johnson & Johnson prays that:

- (1) Plaintiffs take nothing by reason of the Complaint;
- (2) The Complaint be dismissed in its entirety and that a Judgment against Plaintiffs and in favor of Johnson & Johnson be entered;
- (3) Johnson & Johnson be awarded its costs and expenses; and
- (4) This Court award Johnson & Johnson any other and general or specific relief as this Court may deem just and proper.

Respectfully submitted this ____ day of April, 2017.

WILLIAM E., LAWTON, ESQUIRE
Wlawton@drml-law.com

Fla. Bar No.: 0163236
Dean, Ringers, Morgan and Lawton, P.A.
Post Office Box 2928
Orlando, Florida 32802
Phone: (407) 422-4310
Fax: (407) 648-0233

Attorneys for Defendant Johnson & Johnson

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been served via EM/ECF delivery to Douglass A. Kreis, Esq., 17 East Main Street, Suite 200, Pensacola, FL 32502, this the ____ day of April, 2017.

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Attorneys for Defendant Johnson & Johnson

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